Group Art Unit: 1645

Attorney

Docket: 29489

JAN 2 6 2007

In re Applicant:

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Applicant:

Shmuel PIETROKOVSKI et al

Serial No.:

10/534,544

Filed:

May, 10, 2005

For:

CHIMERIC AUTOPROCESSING POLYPEPTIDES

AND USES THEREOF

Examiner:

Not Yet Assigned

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## <u>INFORMATION DISCLOSURE STATEMENT</u>

Sir:

Enclosed is a PTO Form 1449 which lists citations which may be material to the patentability and examination of the above identified application. Also enclosed are copies of the references cited. These are submitted in compliance with the duty of disclosure defined in 37 CFR 1.56. The Examiner is requested to make these citations of official record in this application.

This Information Disclosure Statement under 37 CFR 1.56 is not to be construed as a representation that a search has been made, that additional matter which is material to the examination of this application does not exist, or that any or more of these citations constitutes prior art.

Respectfully submitted,

Martin D. Moynihan Registration No. 40,338

Dated: January 23, 2007



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Substitute for form 1449A/PTO  INFORMATION DISCLOSURE  STATEMENT BY APPLICANT  (use as many sheets as necessary)				Application Number 10/534,544					
				Filing Date	May, 10, 2005				
				First Named Inventor	<u> </u>	ROKOVSKI et al			
				Group Art Unit	1645				
				Examiner Name	Not Yet Assigned				
Sheet	1	Of	4	Attorney Docket Number					
<u> </u>		OTHER PRIOR ART – NON P.	1 -	<u> </u>	·				
Examiner	Cite	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the							
Initials	No.1		=	alog, etc.) date, page(s), volume-issue number(s),					
	1	publisher, city and/or country where published.  Amitai et al. "Distribution and Function of New Bacterial Intein-Like Protein							
	1	Domains", Molecular Microbiology, 47(1): 61-73, 2003.							
	2	Fraser et al. "Novel Neisserial Polypeptides Predicted to Be Useful Antigens for							
	2	Vaccines and Diagnostics", Database EMBL 'Online!, No. AAY75498, 2000.							
	3	Zhang et al "Construction of A Mini-Intein Fusion System to Allow Both Direct							
		Monitoring of Soluble Protein Expression and Rapid Purification of Target							
		Proteins", Gene, 275(2): 241-252, 2001. P.250, l-h Col., § 3 - P.251, r-h Col., § 1,							
		Figs. 1, 3.							
	4	Humphries et al. "Expression of the Class 1 Outer-Membrane Protein of Neisseria							
		Meningitidis in Escherichia Coli and Purification Using A Self-Cleavable Affinity							
		Tag", Protein Expression and Purification, 26(2): 243-248, 2002. P.247, r-h Col., §							
		2 - P.248, l-h Col., § 2, Fig. 1.							
	5	Aspöck et al. "Caenorhabditis Elegans Has Scores of Hedgehog-Related Genes:							
		Sequence and Expression Analysis", Genome Research, 9(10): 909-923, 1999.							
	6	Pietrokovski "Intein Spread and Extinction in Evolution", Trends in Genetics							
		17(8): 465-472, 2001.							
	7	Buell et al. "Filamentous Hemagglutinin, Intein-Containing, Putative", Database							
		Trembl 'Online!, No. Q880E1, 2003.							
	8	Brown et al. "Hypothetical Protein SCP1.201", Database Trembl 'Online!, No.							
-		Q9ACV2, 2003.							
	9	Ren "Probable Phenazine Biosynthesis Family Protein", Database Trembl 'Online!,							
		No. Q8EZX6, 2003.  Classians et al. "Hymothetical Protein PR6107" Database Trembl 'Online! No.							
	10	Gloeckner et al. "Hypothetical Protein RB6107", Database Trembl 'Online!, No.							
	11	Q7UQT4, 2003.	A 3/20/	Oll Dotahaaa Trambi lOnlin	nal Ma				
	11	Omura et al. "Hypothetical Protein SAV200", Database Trembl. 'Online!, No. Q82RE3, 2003.							
	12	Omura et al. "Hypothetical Protein Sa	4 V/28/	6" Database Trembl 'Onlir	nel No				
	12	Q82R58, 2003.	4 7 20	o, Database Fremoi. Offin	10:, 140.				
	13		A V 529	92" Database Trembl 'Onli	ne! No				
		Omura et al. "Hypothetical Protein SAV5292", Database Trembl 'Online!, No. Q82CQ1, 2003.							
	14	Ren "Hypothetical Protein LA3719",	Datab	pase Trembl 'Online! No. C	08EZY2				
	* 1	2003.			~,				
	15	Dassa et al. "Protein Splicing and Auto-Cleavage of Bacterial Intein-Like Domains							
		Lacking A C'-Flanking Nucleophilic Residue", The Journal of Biological							
		Chemistry, 279(31): 32001-32007, 20		,					
	16	Dassa et al. "New Type of Polyubiqu		ike Genes With Intein-Like					
		Autoprocessing Domains", Trends in Genetics, 20(11): 538-542, 2004.							

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	Substitute for form 1449A/PTO			Complete if Known Application Number 10/534,544				
INTECDATATION DICCI OCUDE				Filing Date	May, 10, 2005			
INFORMATION DISCLOSURE				First Named Inventor	<del></del>	TROKOVSKI et al		
STATEMENT BY APPLICANT			Group Art Unit	1645				
(use as many sheets as necessary)			Examiner Name	Not Yet Ass	igned			
Sheet	2	Of	4	Attorney Docket Number	29489			
		OTHER PRIOR ART – NON PA	TEN	IT LITERATURE DOCU	MENTS			
	17	Southworth et al. "Rescue of Protein S						
		Magnetotacticum Intein-Like Element 32(Part 2): 250-254, 2004.						
	18	Dassa et al. "Origin and Evolution of I	ntei	ns and Other Hint Domain	s". Nucleic			
		Acids and Molecular Biology, 16: 209			- ,			
	19	Belfort et al. "Homing Endonucleases: Keeping the House in Order", Nucleic						
		Acids Research, 25(17): 3379-3388, 1		•				
	20	Bürglin "Warthog and Groundhog, No			hog",			
		Current Biology, 6(9): 1047-1950, 199						
<del>-</del>	21	Cattoli et al. "Separation of MBP Fusion Proteins Through Affinity						
		Membranes", Biotechnological Progre						
	22	Chong et al. "Protein Splicing Involving			iae VMA			
		Intein", The Journal of Biological Che	emist	try, 271(36): 22159-22168	, 1996.			
	23	Chong et al. "Single-Column Purificat						
		Self-Cleavable Affinity Tag Derived From A Protein Splicing Element", Gene,						
	ļ	192: 271-281, 1997.						
·····	24	Chong et al. "Protein Splicing of the Saccharomyces Cerevisiae VMA Intein						
		Without the Endonuclease Motifs", Th						
	į.	272(25): 15587-15590, 1997.						
	25	Chong et al. "Modulation of Protein Splicing of the Saccharomyces Cerevisiae						
		Vacuolar Membrane ATPase Intein", The Journal of Biological Chemistry,						
		273(17): 10567-10577, 1998.						
<u>-</u>	26	Chong et al. "Utilizing the C-Terminal Cleavage Activity of A Prtoein Splicing						
		Element to Purify Recombinant Proteins in A Single Chromatographic Step",						
	Ì	Nucleic Acids Research, 26(22): 5109	9-511	15, 1998.				
	27	Clonis "High-Performance Affinity C	hron	natography (HPAC)", HPL	C of			
		Macromolecules: A Practical Approach	ch, Il	RL Press, Chap.6: 157-182	2, 1989.			
•	28	Coote "Structural and Functional Rela						
		Determinants of Gram-Negative Bacteria", FEMS Microbiology Reviews, 88:						
		137-162, 1992.						
·=	29	Dalgaard et al. "Statistical Modeling,	Phyl	logenetic Analysis and Stru	ucture			
		Prediction of A Protein Splicing Domain Common to Inteins and Hedgehog						
		Proteins", Journal of Computational E						
	30	Derbyshire et al. "Genetic Definition	of A	Protein-Splicing Domain:	<b>Functional</b>			
		Mini-Inteins Support Structure Predic	tion	s and A Model for Intein E	Evolution",			
		Proc. Natl. Acad. Sci. USA, 94: 1146	6-11	471, 1997.				
	31	Fouts et al. "Genomewide Identificati	on o	f Pseudomonas Syringae F	v. Tomato			
		DC3000 Promoters Controlled by the						
		Natl. Acad. Sci. USA, 99(4): 2275-22	_					
· <del>-</del>	32	Gimble et al. "Homing of A DNA En			ene			
	-	Conversion in Saccharomyces Cerevi						
	<del></del>							
Signature		Considered						

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	****	ubstitute for form 1449A/PTO	Com	plete if Known					
,	-		Application Number	10/534,544					
	INFOR	MATION DISCLOSURE	Filing Date	May, 10, 2005					
	STATE	EMENT BY APPLICANT	First Named Inventor	Shmuel PIETROKOVSKI et al					
(use as many sheets as necessary)			Group Art Unit Examiner Name	Not Yet Assigned					
Sheet	3	Of 4	Attorney Docket Number	29489					
Silect	<u> </u>	OTHER PRIOR ART – NON PATENT							
	33	Guan et al. "Production of Extracellular De	<del> </del>						
		Using Maltose-Binding Protein Fusion Sys							
		Purification, 26: 229-234, 2002.	stem, i rotem Expression a						
	34	Tanaka Hall et al. "Crystal Structure of A	Hedgehog Autoprocessing						
		Domain: Homology Between Hedgehog as							
		91: 85-97, 1997.	ina outrophiom8 riconno ,						
	35	Hammerschmidt et al. "The World Accord	ling to Hedgehog". Trends	in					
		Genetics, 13(1): 14-21, 1997.							
	36	Haselkorn et al. "The Rhodobacter Capsula	atus Genome". Photosynthe	esis					
		Research, 70: 43-52, 2001.	,						
	37	Hirata et al. "Molecular Structure of A Ger	ne, VMA1, Encoding the						
		Catalytic Subunit of H+-Translocating Ad	,	om					
		Vacuolar Membranes of Saccharomyces Cerevisiae", The Jornal of							
		Biological Chemistry, 265(12): 6726-6733, 1990.							
	38	Jack "Immunoaffinity Chromatography", N	Molecular Biotechnology, 1	: 59-					
		86, 1994.							
	39	James et al. "The Biology of E Colicins: P	aradigms and Paradoxes",						
		Microbiology, 142: 1569-1580, 1996.							
	40	Janson et al. "Packings in Affinity Chroma	atography", Techniques, P.7	747-					
		781, 1990.							
	41	Jensen et al. "Delayed Extraction Improve	<del>-</del>						
		by Matrix-Assisted Laser Desorption/Ionization Peptide Maps", Rapid							
		Communications in Mass Spectrometry, 10							
	42	Kane et al. "Protein Splicing Converts the	to the						
		69-KD Subunit of the Vacuolar H\$^+\$-Ad							
	40	Science, 250(4981): 651-657, 1990.	A ('II' T A ('I I OD)						
	43	Kaufmann et al. "Crystal Structure of the A	•						
		Single-Chain Fragment Complexed to Its A	Antigen", Journal of Molec	ular					
	4.4	Biology, 318: 135-147, 2002.	Jacometica /Ionization Mass						
	44	Kussmann et al. "Matrix-Assisted Laser D Spectrometry Sample Preparation Techniq	_	Pontido					
		and Protein Analytes", Journal of Mass Sp	<del>-</del>						
	45	Narayanan "Preparative Affinity Chromato		<u> </u>					
	73	Chromatography A, 658: 237-258, 1994.	ography of Froteins, Journ						
	46	Nilsson et al. "Affinity Fusion Strategies for	or Detection Purification	and					
	'	Immobilization of Recombinant Proteins",	•						
		Purification, 11: 1-16, 1997.	, x rototti Ziiprotti tii tii						
·	47	Nisnevitch et al. "The Solid Phase in Affin	nity Chromatography: Strate	egies					
		for Antibody Attachement", Journal of Bio							
		Methods, 49: 467-480, 2001.							
<del>,,,=</del>	48	Noren et al. "Dissecting the Chemistry of I	Protein Splicing and Its						
		Applications", Angewandte Chemie, Intern		66,					
		2000.	•						
Signature		Considered							

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	INFOR	MATION DISCLOSURE	Filing Date First Named Inventor	May, 10, 2	UUS ETROKOVSKI et al			
	STATE	MENT BY APPLICANT	Group Art Unit	1645	LIKOROVSKICI al			
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heet	4	Of 4	Attorney Docket Number					
<u>-</u>		OTHER PRIOR ART – NON PATENT	LITERATURE DOCU	MENTS				
	49	Paulus "Protein Splicing and Related Form	s of Protein Autoprocess	ing",				
		Annual Review of Biochemistry, 69: 447-4	<b>-</b>					
	50	Perler et al. "Protein Splicing and Its Appli		n in				
		Biotechnology, 11: 377-383, 2000.						
	51							
	52	Pietrokovski "Conserved Sequence Features of Inteins (Protein Introns) and						
		Their Use in Identifying New Inteins and Related Proteins", Protein Science, 3:						
		2340-2350, 1994.						
	53	Pietrokovski "Modular Organization of Inteins and C-Terminal Autocatalytic						
		Domains", Protein Science, 7: 64-71, 1998						
	54	Porter et al. "Hedgehog Patterning Activity: Role of A Lipophilic Modification Mediated by the Carboxy-Terminal Auotprocessing Domain", Cell, 86: 21-34,						
		1996.			<u></u>			
	55	Porter et al. "Cholesterol Modification of Hedgehog Signaling Proteins in						
		Animal Development", Science, 274(5285): 255-259, 1996.						
	56	Sano et al. "Streptavidin-Containing Chimeric Proteins: Design and						
		Production", Methods in Enzymology, 326(19): 305-311, 2000.						
	57	Sano et al. "Genetic Engineering of Streptavidin, A Versatile Affinity Tag",						
		Journal of Chromatography B, 715: 85-91, 1998.						
	58	Schmidt et al. "Molecular Interaction Betw						
		and Its Cognate Target, Strepatvidin", Jour						
		766, 1996.						
	59	Schmidt et al. "The Random Peptide Librar						
		Terminal Affinity Peptide, Useful for the Detection and Purification of A						
		Functional Ig Fv Fragment", Protein Engineering, 6(1): 109-122, 1993.						
	60	Sheibani "Prolkaryotic Gene Fusion Expression System and Their Use in						
		Structural and Functional Studies of Proteins", Preparations in Biochemistry &						
		Biotechnology, 29(1): 77-90, 1999.						
	61	Shingledecker et al. "Molecular Dissection of the Myobacterium Tuberculosis						
		RecA Intein: Design of A Minimal Intein and of A Trans-Splicing System						
		Involving Two Intein Fragments", Gene, 207: 187-195, 1998.						
	62	Skerra et al. "Applications of A Peptide Ligand for Strepatvidin: The Strep-						
		Tag", Biomolecular Engineering, 16: 79-86, 1999.						
	63	Stoddard et al. "Breaking Up Is Hard to Do", Nature Structural Biology, 5(1):						
		3-5, 1998.						
	64	Vorm et al. "Improved Resolution and Ver						
		of Matrix Surfaces Made by Fast Evaporation", Analytical Chemistry, 66(19):						
	(5	3281-3287, 1994.						
	65	Wilchek et al. "An Overview of Affinity C						
		Molecular Biology, 147: 1-6, 2000.  Xu et al. "The Mechanism of Protein Splicing and Its Modulation by						
	66	•						
		Mutation", The EMBO Journal, 15(19): 51	40-3133, 1990.					
	Ī				I			

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